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## **DETAILED ACTION**

### **Status of the Application**

Receipt of the Request for Continued Examination (RCE) under 37 CFR 1.114, the Amendment and Applicant's Arguments/Remarks, all filed 07/15/08 is acknowledged.

Claims 25, 30-32 and 34 are pending in this action. Claim 25 has been amended via Applicant's and Examiner's amendment. New claim 34 has been added. Claims 27 and 33 have been cancelled herein via Examiner's Amendment. Claims 1-24, 26, 28 and 29 have previously been cancelled. Claims 25, 30-32 and 34 are allowed.

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 15 July 2008 has been entered.

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### **EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Robert Auerbach on 30 September 2008.

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The application has been amended as follows:

**In the Specification:**

Before the heading of "Background of the invention," please insert:

**--CROSS REFERENCE**

**This is a divisional application of application serial number 09/851,877, filed on May 9, 2001, now U.S. Patent No. 6,656,506.--**

Page 16, line 2 will read as follows: **--09/750,595, now U.S. Patent No. 6,730,228--**.

Page 16, in line 2 the phrase "(Attorney Docket No. 16315v)" has been deleted.

**In the Claims:**

In Claim 25, lines 2-3, after the term 'fluid form of', the phrase "an implantable medical device" has been deleted and replaced with **--a stent--**.

In Claim 25, line 8, after the term 'added thereto to', the phrase "an implantable medical device" has been deleted and replaced with **--a stent--**.

**Claims 27 and 33 have been cancelled.**

***Allowable Subject Matter***

Claims 25, 30-32 and 34 are allowed.

The following is an examiner's statement of reasons for allowance:

The primary reasons for allowance are that the prior art of record (Golomb *et al.* U.S. Patent No. 6,719,998) fails to disclose or teach the instant drug-loaded particle formulation method comprising process steps which include use of a multi-polymer system whereby polymer particles and a therapeutic substance are combined and suspended into a polymeric material dissolved in the solvent. The prior art also fails to disclose or teach application of a fluid form of the coating material to a medical device, such as a stent and solidifying the coating material by allowing evaporation of the solvent. The prior art further fails to disclose or teach polymeric particles made using a water-in-oil emulsion method. The instant invention provides for the placement and combination of polymer plus therapeutic substance prior to mixing into an additional polymer solution. In contrast, the Golomb reference teaches a one-polymer system rather than a multi-polymer system as claimed. The multi-polymer system demonstrates an improvement over prior art formulations in that it is effective to allow coating of microparticles containing a therapeutic agent onto a stent using a solvent evaporation method.

In the telephonic interview held on September 30, 2008 between Applicant's representative (Robert Auerbach) and the Examiner of record (H. Sheikh), suggestions were made by the Examiner to limit and replace the "implantable medical device" in claim 25 to a "stent"; and (2) To employ language reciting a Markush group of "drug, and/or therapeutic substance and radioactive isotope" in claim 25; and (3) To cancel claims 27 and 33. Applicant's

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representative adopted the suggestions made by the Examiner. With regards to (2) above, Applicant indicated that they will cancel claim 33 since "drug" as defined in the instant specification includes all therapeutic agents, diagnostic agents/reagents and other similar chemical/biological agents. Diagnostic agents would include radioactive isotopes (see pg. 4 of specification). Accordingly, the instant invention is rendered non-obvious and *patentable* over the cited art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### **Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday-Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley, can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/

Primary Examiner, Art Unit 1618

*hns*

September 30, 2008